

REMARKS

Claim Status

Claim 1 has been amended to recite that the feed composition comprises an animal feed as well as about 0.25 to about 10% by weight of triglycerides containing C₄-C₁₂ medium chain fatty acids and about 100 to about 10,000 ppm active lipolytic enzyme. Support for the amendments is found in Example 1 and Example 2 (for animal feed component); Example 1, Table 1 (for weight concentration unit of g/100 g); and on page 1, lines 7-11 and page 3, line 31 through page 4, line 1 (for triglycerides containing C₄-C₁₂ medium chain fatty acids) of the instant specification. Claim 1 has further been amended to specify that the feed composition is a dry composition. Support for this dry form of the composition is found on page 11, line 33 and page 15, line 18 of the instant specification.

Claims 14 and 20 have been cancelled. As a result of the cancellation of claim 20, claim 21 has been amended to correct the dependency.

Claims 27-32 have been added. New claim 27 is directed to a technical feature that is excised from claim 1 as presently amended. Support for new claims 28-31 is found on page 10, lines 20-21; page 11, lines 6 and 27-29; page 14, lines 24-27 and page 18, lines 31-32 of the instant specification. New claim 32 further limits the feed composition of claim 1 to comprise about 2.5% to about 10% by weight of triglycerides containing C₄-C₁₂ medium chain fatty acids. Support for this new claim is found in Experiment 4 and Table 9 of the present specification.

Pursuant to 37 C.F.R. §1.118(a), Applicants respectfully submit that the above amendments do not introduce any new material into the application. With the present amendments, 15 claims are pending in the application, namely, claims 1-3, 9-12, 21 and 26-32.

Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1-3, 9-12, 14, 20-21 and 26 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. In response, Applicants have amended claims 1 and 21 as well as cancelled claims 14 and 20 to address the issues raised by the Examiner.

In particular, claim 1 as presently amended no longer recites the phrases “consisting essentially of” and “industrially prepared”. In addition, the amended claim 1 corrects the use of the singular “triglyceride” to be plural “triglycerides” as supported by the originally filed specification.

Regarding the term “ppm” cited in claim 1, Applicants again reiterate from the previous responses that such term is repeatedly used in the instant specification to refer to the concentration of the enzyme(s) and that one of ordinary skill in the art would know what the term means and how to measure the concentration of the enzyme(s) in ppm. Applicants further submit that 100 ppm and 10,000 ppm are equivalent to 0.01% by weight [i.e., $(100/10^{-6}) \times 100\%$] and 10% by weight [i.e., $(10000/10^{-6}) \times 100\%$], respectively. Applicants are willing to amend the claim to recite above equivalent conventional concentrations in lieu of parts per million if preferred by the Examiner.

While Applicants acknowledge that units of activity are generally used for characterizing enzymes, it is not the only term to describe enzymes. Enzymes can be described in their concentrations, and parts per million (“ppm”) is routinely used by one of ordinary skill in the art for a measurement of enzyme concentrations. For example, U.S. Pat. Nos. 5,968,792 and 6,620,605 use “ppm” when describing and claiming concentrations of its respective enzymes, of which Applicants point out that the same Examiner was the primary Examiner on U.S. Pat. No.

5,968,792. Another example is Tang *et al.* cited by the Examiner in the instant case, which describes that human milk contains about 0.1 mg BAL /ml (i.e., about 100 ppm as stated by the Examiner) of human skim milk. In view of these examples, Applicants respectfully request that the Examiner remove her repeated rejection on the use of “ppm”.

It is believed that the claims as presently amended are now definite and that the rejection under 35 U.S.C. § 112, second paragraph is now overcome.

Rejections under 35 U.S.C. § 102

Claims 1-3, 8-11 and 20-25 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by breast milk from humans and other animals as evidenced by Tang *et al.* and Hurley. Applicants respectfully traverse this rejection.

Claim 1 as presently amended refers to a feed composition (emphasis added) comprising an animal feed, about 0.25 to about 10% triglycerides containing C₄-C₁₂ medium chain fatty acids and about 100 to about 10,000 ppm active lipolytic enzyme, wherein the feed composition is dry.

Tang *et al.* discloses a dietary composition comprising a nutritional base containing fats and an effective amount of bile salt activated lipase, wherein the preferred base is in a liquid form, i.e., milk or formula. *See* col. 4, lines 27-28. Tang *et al.* does not disclose a feed composition that is dry and comprises an animal feed as well as triglycerides and active lipolytic enzyme.

Hurley is a general disclosure on liquid human breast milk and lactation. In particular, Hurley discloses that human or bovine breast milk contains 4% triglycerides. However, Hurley does not disclose a feed composition that is dry and comprises an animal feed as well as triglycerides and active lipolytic enzyme.

Although Tang *et al.* and Hurley together might teach that breast milk from humans and other animals contains about 4% triglycerides and about 100 ppm of active bile-salt activated lipase, neither reference teaches a feed composition comprising an animal feed in addition to a mixture of about 0.25% to about 10% triglycerides and about 100 ppm to about 10000 ppm active lipolytic enzyme. Furthermore, either Tang *et al.* or Hurley provides motivation of combining an animal feed with mixtures of triglycerides and lipase. Thus, this rejection should be traversed.

Rejection under 35 U.S.C. § 103

Claims 1-3, 8-12, 14 and 20-25 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hull *et al.* taken with Haas *et al.* and Tang *et al.* Applicants respectfully traverse this rejection.

Applicants first note that the Examiner appears to have inadvertently left out the references for this 35 U.S.C. 103(a) rejection, and that the Hull *et al.*, Haas *et al.* and Tang *et al.* references, cited by the Examiner in the previous Office Actions, are assumed to be the missing references and again discussed in the following remarks.

Claim 1 has been amended to recite a feed composition (emphasis added) comprising an animal feed, about 0.25 to about 10% triglycerides containing C₄-C₁₂ medium chain fatty acids, and about 100 to about 10,000 ppm active lipolytic enzyme, wherein the feed composition is dry.

Hull *et al.* discloses a method of producing sweet cream buttermilk from lipolyzed creams. The resultant buttermilk in Hull *et al.* does not appear to contain an animal feed. Thus, Hull *et al.* does not teach nor suggest a feed composition as presently claimed.

Haas *et al.* discloses a composition comprising fat and protein, which has been conditioned by emulsifying the fat and treating the mixture with lipase and protease. *See* Abstract. During the treatment, the fat reacts with the lipase to produce free fatty acids and mono- and diglycerides (emphasis added). *See* Col. 2, lines 17-19. Clearly, Haas *et al.* does not teach or suggest a dry feed composition comprising an animal feed, triglycerides (emphasis added) containing C₄-C₁₂ medium chain fatty acids, and lipolytic enzymes.

Tang *et al.* is discussed above.

None of the Hull *et al.*, Haas *et al.* and Tang *et al.* teaches or suggests a feed composition comprising an animal feed, about 0.25 to about 10% triglycerides containing C₄-C₁₂ medium chain fatty acids, and about 100 to about 10,000 ppm active lipolytic enzyme. Even if one of ordinary skill in the art is motivated to combine the teachings of Hull *et al.*, Haas *et al.* and Tang *et al.*, he or she would not have produced the present invention as claimed.

The feed composition as claimed in the present application alleviates and/or prevents health problems encountered by animals in their early growth. The feed composition as presently claimed is dry, which further provides the advantages that the enzymes and triglycerides present therein are stable and not easily degraded. As a result, the feed composition

as a whole can be easily handled and has the economical advantage of long term conservation without spoiling of the feed.

The health benefits of an animal feed composition comprising C₄-C₁₂ medium chain fatty acid (MCFA)-containing triglycerides and lipolytic enzymes are clearly demonstrated in the present specification, for instance, in Example 2, Tables 3 and 4, respectively, on pages 12 and 13. The combination of C₄-C₁₂ medium chain fatty acid-containing triglycerides and exogenous lipolytic enzymes surprisingly results in a physiological environment in the stomach which regulates and stabilizes the gastrointestinal microflora. This effect, combined with the fact that an easily digestible and metabolizable source of energy is provided, surprisingly results in a marked improvement of the growth which is comparable with the growth promotion obtained with the commonly used (and contested) antibiotics and other growth enhancers without negative side effects for the animal, the feed industry and the consumer. The present feed composition shows an unexpectedly high bacteriostatic and bactericidal activity against Gram-positive and Gram-negative bacteria (*see* present specification, page 7, lines 17-18; Experiment 4; Table 9.)

In view of the above remarks, neither the feed composition as presently claimed, nor the above-mentioned unexpected benefits provided by such compositions, would have been apparent from Hull *et al.*, Haas *et al.*, and Tang *et al.*, alone or combined. Therefore, Hull *et al.* taken with Haas *et al.* and Tang *et al.* would not have rendered obvious the present invention as claimed. Applicants respectfully request that the rejection under 35 U.S.C. 103 be traversed.

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This document is filed timely. No fee is believed to be due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Commissioner is authorized to deduct said fees from Deposit Account No. 08-3038/13475.0003.PCUS00.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. Wendy Davis". The signature is fluid and cursive, with a large initial "J" and a stylized "D" at the end.

J. Wendy Davis, Ph.D.

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